A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2010 has been entered.

Claims 1-5, 7, 9-22, 24-27, 29, 31-44 and 46-49 are pending in this application.

Applicant's amendment of 4/7/2010 added a claim feature, adjusting the pH wherein the composition retains at least 90% activity when stored for 770 days.

Because of this feature, all outstanding grounds of rejection are withdrawn. However, said added claim feature raises a new matter issue, which is discussed below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 9-22, 24-27, 29, 31-44 and 46-49 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims have been amended to recite a stability feature, wherein the composition retains "at least 90% activity when stored for 770 days."

- (1) The entire original disclosure has been reviewed and there is only one specific mention of 770 days: Table 3 on page 12. There, days to 90% (i.e. days to 10% degradation) was 770. This means that "at least 90%" is too broad for this disclosure because original data or original disclosure of 90% at 770 days does not convey 91% (i.e. 9% degradation), 92% (8% degradation), 99% (1% degradation), and so on at 770 days.
- (2) As noted in the previous Office action of 3/5/2009, compositions 6, 7 and 11 are directed to the following components:

I ludua man manavida	Compositions 6, 7, 11	Breath of the claims
Hydrogen peroxide	1.15%	>0 to 2%
1-glycerolmonolaurate (C12)	7%	1-35% monoglyceride(s) of
1-glycerolmonomyristate (C14)	21%	fatty acid
Myrj 59 (POE stearate)	1%	not claimed
Popylene glycol	2 %	only in claims 22, 44
Sodium stannate	0.04%	0.005 to 0.05% any tin salt
Salicylic acid	0.1%	0.02 to 0.5%
Na pyrophosphate	0.025%	only in claims 15, 37
Sulfuric acid	0.038%	not claimed
EDTA	0.05%	only in claims 16, 38
Oxalic acid	0.14%	0.05 to 0.5% any
		polycarboxylic acid
Citric acid	0.9%	reads on polycarboxylic or
		citrate buffer
NaOH		to pH 3,7, 4.5 or 4.6;
110011		adjust to bet. 3.7 and 4.6;
		adjust to 3.7 to 4.6;
		has a pH of 3.7 to 4.6,
		•
		has an initial pH of 3.7 to
		4.6

Therefore, current claims, with their new feature of "at least 90% activity when stored for 770 days" cannot find adequate written descriptive support from compositions 6, 7 and 11 because those compositions were very specific in their components, many of which are not in the current claims. It is not adequately conveyed from the originally disclosed data for compositions 6, 7 and 11 that the much more broadly defined compositions as those currently claimed would provide the same result of "at least 90% activity when stored for 770 days."

(3) Also, adjusting the pH to "between 3.7 and 4.6" (emphasis added, see claim 1) was not originally disclosed for the newly claimed feature of 90% activity for 770 days of storage because such stability was obtained only by adjusting to pH 3.7 to 4.6 (see compositions 6, 7 and 11 in Table 3).

For these reasons, the amended claims fail to find adequate descriptive support from the originally filed disclosure. The claims must be rejected as failing to comply with the written description requirement of 35 USC 112, first paragraph.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on (571)272-0646.

The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

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/John Pak/ Primary Examiner, Art Unit 1616